

# Financial Results for the First Nine Months of Fiscal Year Ending December 2018

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- ※ This material is prepared based on Japan GAAP.
- ※ Amounts are rounded down to the nearest million yen.

October 31, 2018



**TORII PHARMACEUTICAL CO., LTD.**

# I Summary Information

## ① Financial Results

The forecasts for the FY2018 have been changed from the previous forecasts announced at the first six months of FY2018 financial results announcement on July 30, 2018.

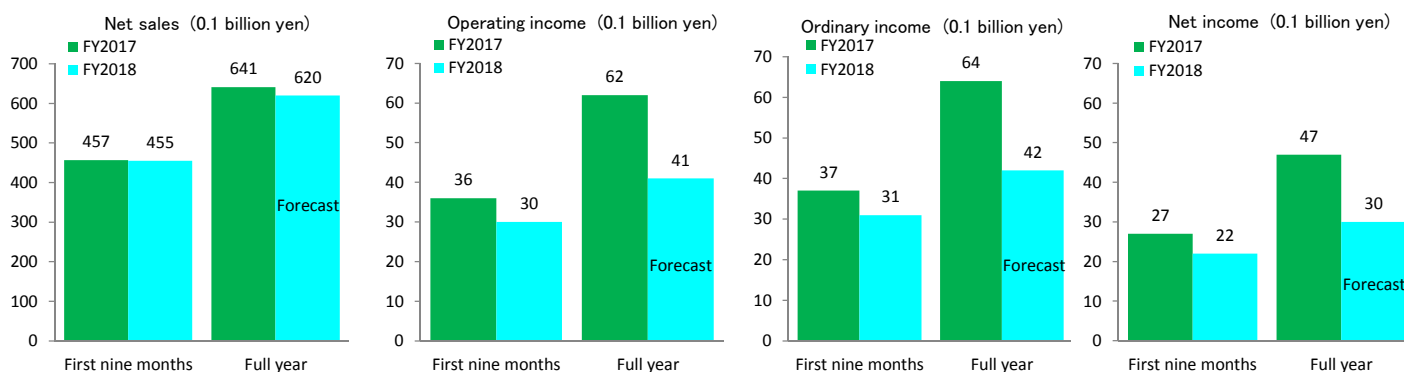
(Millions of Yen)	FY2017		FY2018		Change B-A	Change (%) (B-A)/A	FY2017 Full year	FY2018 revised forecast	Progress ratio (%) B/C
	First nine months A	First nine months B	First nine months C	First nine months D					
Net sales	45,726	45,543	64,135	62,000	(182)	(0.4)	64,135	62,000	73.5
Operating income	3,660	3,044	6,281	4,100	(616)	(16.8)	6,281	4,100	74.2
Ordinary income	3,735	3,134	6,403	4,200	(600)	(16.1)	6,403	4,200	74.6
Net income	2,771	2,248	4,718	3,000	(523)	(18.9)	4,718	3,000	75.0
<b>(Reference)</b>									
R&D expenses	3,516	3,101	4,608	4,400	(415)	(11.8)	4,608	4,400	70.5
Earnings per share (EPS) (¥)	98.83	80.14	168.22	106.93	(18.69)		168.22	106.93	
Return on equity (ROE) (%)	3.3	2.6	5.5	—	(0.7)		5.5	—	
Ratio of ordinary income to total assets (%)	3.8	3.0	6.3	—	(0.8)		6.3	—	
Ratio of operating income to net sales (%)	8.0	6.7	9.8	—	(1.3)		9.8	—	
Return on assets (ROA) (%)	2.8	2.1	4.6	—	(0.7)		4.6	—	

### (Cautionary Note Regarding FY2018 Forecasts)

In August 2018, Japan Tobacco Inc. (JT) signed a non-binding letter of intent (LOI) for initiating a discussion with Gilead Sciences, Inc. (Gilead) to terminate the license agreements for six anti-HIV drugs ("Viread Tablets" "Emtriva Capsules" "Truvada Combination Tablets" "Stribild Combination Tablets" "Genvoya Combination Tablets" and "Descovy Combination Tablets"). The anti-HIV drugs were developed by Gilead, and have been exclusively licensed to JT to develop and commercialize in Japan.

Torii and JT signed a non-binding LOI for initiating a discussion to terminate the license agreements by which JT grants Torii the exclusive rights to market the anti-HIV drugs in Japan.

The effect of the LOI on the business performance of Torii has not been incorporated in the forecasts for the FY2018. Torii will make a further announcement regarding this subject when appropriate.



## ② Financial Conditions

(Millions of Yen)	December 31,		September 30,		Change B-A	Change (%) (B-A)/A
	2017 A	2018 B	2018 C	2018 D		
Total assets	104,741	104,754	104,754	104,754	12	0.0
Total equity	87,119	88,184	88,184	88,184	1,065	1.2
Equity ratio (%)	83.2	84.2	84.2	84.2	1.0	
Book value per share (BPS) (¥)	3,105.68	3,142.16	3,142.16	3,142.16	36.48	

## II Financial Results for the First Nine Months of FY2018

### ① Statement of Income

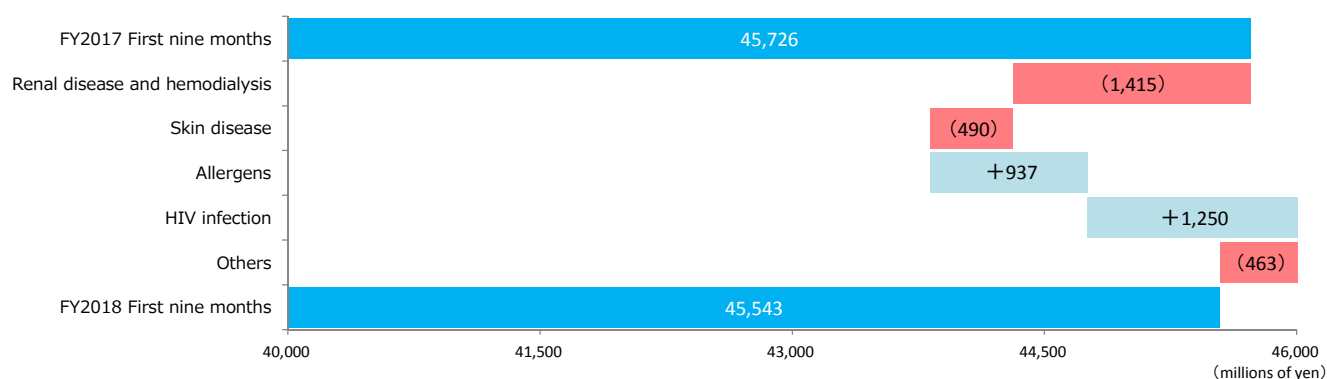
<i>(Millions of Yen)</i>	FY2017		FY2018		Change <i>B-A</i>	Change (%) <i>(B-A)/A</i>
	First nine months <i>A</i>	First nine months <i>B</i>	First nine months <i>B</i>	First nine months <i>A</i>		
Net sales	45,726	45,543	45,543	45,726	(182)	(0.4)
Sales of products	44,930	44,921	44,921	44,930	(8)	(0.0)
Renal disease and hemodialysis	17,995	16,579	16,579	17,995	(1,415)	(7.9)
Skin disease	7,235	6,744	6,744	7,235	(490)	(6.8)
Allergens	1,437	2,374	2,374	1,437	937	65.2
HIV infection	14,043	15,293	15,293	14,043	1,250	8.9
Other	4,218	3,928	3,928	4,218	(290)	(6.9)
Other sales	795	622	622	795	(173)	(21.7)
Cost of sales	22,602	23,547	23,547	22,602	945	4.2
Cost of products sold	22,561	23,507	23,507	22,561	945	4.2
Other cost	40	40	40	40	(0)	(0.8)
Gross profit	23,123	21,996	21,996	23,123	(1,127)	(4.9)
Selling, general and administrative expenses	19,463	18,952	18,952	19,463	(511)	(2.6)
R&D expenses	3,516	3,101	3,101	3,516	(415)	(11.8)
Others	15,946	15,850	15,850	15,946	(95)	(0.6)
Operating income	3,660	3,044	3,044	3,660	(616)	(16.8)
Non-operating income	86	94	94	86	7	–
Non-operating expenses	12	4	4	12	(7)	–
Ordinary income	3,735	3,134	3,134	3,735	(600)	(16.1)
Extraordinary loss	20	24	24	20	3	–
Income before income taxes	3,714	3,109	3,109	3,714	(604)	(16.3)
Income taxes	942	861	861	942	(81)	–
Net income	2,771	2,248	2,248	2,771	(523)	(18.9)

### (Reference) Ratio to net sales

<i>(%)</i>	FY2017		FY2018		Change <i>B-A</i>
	First nine months <i>A</i>	First nine months <i>B</i>	First nine months <i>B</i>	First nine months <i>A</i>	
Cost of sales	49.4	51.7	51.7	49.4	2.3
SG&A	42.6	41.6	41.6	42.6	(1.0)
R&D expenses	7.7	6.8	6.8	7.7	(0.9)
Operating income	8.0	6.7	6.7	8.0	(1.3)
Ordinary income	8.2	6.9	6.9	8.2	(1.3)
Net income	6.1	4.9	4.9	6.1	(1.2)

**[Factors in increase/decrease compared with the same term of the last fiscal year]**

**Net Sales (¥45,543 million : Decrease ¥182 million year-on-year)**



**Major factors in increase/decrease**

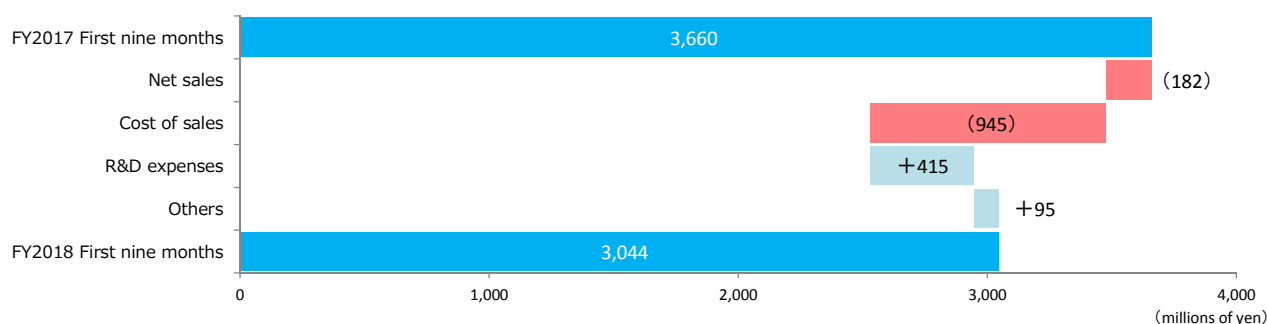
Sales of products : Decrease with the drug price revision implemented on April 1, 2018

Increase with increase in sales quantity

Renal disease and hemodialysis	: REMICH	Decrease	¥ 784 million	FUTHAN	Decrease	¥ 598 million
	: URINORM	Decrease	¥ 238 million	Riona	Increase	¥ 316 million
Skin disease	: ANTEBATE	Decrease	¥ 502 million			
Allergens	: MITICURE	Increase	¥ 446 million	CEDARTOLEN	Increase	¥ 376 million
HIV infection	: Descovy	Increase	¥ 2,792 million	Genvoya	Increase	¥ 836 million
	: Truvada	Decrease	¥ 2,285 million			
Others	: Commission income	Decrease	¥ 145 million			

※ For details, please refer to "② Sales of Products" on page 4.

**Operating income (¥3,044 million : Decrease ¥616 million year-on-year)**



**Major factors in increase/decrease**

Cost of sales : Increase with increase in sales quantity and disposal of excess cedar pollen inventory

R&D expenses : Decrease in clinical study expenses (TO-206, TO-203 House dust mite induced allergic rhinitis in children) and co-development expenses (JTE-052)  
Increase in co-development expenses (JTS-661)

Others : Decrease in administrative expenses

**Ordinary income (¥3,134 million : Decrease ¥600 million year-on-year)**

Special remarks: None

**Net income (¥2,248 million : Decrease ¥523 million year-on-year)**

Special remarks: None

## ② Sales of Products

<i>(Millions of Yen)</i>	FY2017	FY2018	Change B-A	Change (%) (B-A)/A
	First nine months A	First nine months B		
<b>Sales of Products</b>	44,930	44,921	(8)	(0.0)
REMITCH Oral anti-pruritus agent [Renal disease and hemodialysis]	9,828	9,043	(784)	(8.0)
Descovy Antiviral agent for HIV [HIV infection]	6,035	8,827	2,792	46.3
Genvoya Antiviral agent for HIV [HIV infection]	4,410	5,246	836	19.0
Riona Agent for hyperphosphatemia [Renal disease and hemodialysis]	4,438	4,754	316	7.1
ANTEBATE ※ Topical corticosteroid [Skin disease]	4,559	4,057	(502)	(11.0)
BIO-THREE Viable bacterial preparations [Other]	1,824	1,923	98	5.4
KAYEXALATE ※ Agent for hyperkalemia [Renal disease and hemodialysis]	1,540	1,430	(110)	(7.2)
CEDARTOLEN ※ Japanese cedar pollinosis (Allergen Immunotherapy) [Allergens]	883	1,260	376	42.7
LOCOID ※ Topical corticosteroid [Skin disease]	1,030	1,133	103	10.1
ZEFNART Topical antifungal agent [Skin disease]	1,107	1,117	9	0.8
Truvada Antiviral agent for HIV [HIV infection]	3,372	1,086	(2,285)	(67.8)
FUTHAN ※ Protease inhibitor [Renal disease and hemodialysis]	1,435	837	(598)	(41.7)
MITICURE ※ House dust mite allergy (Allergen Immunotherapy) [Allergens]	295	741	446	151.0
Magsent Tocolysis in threatened premature labor Eclampsia-suppressing and treatment [Other]	789	693	(95)	(12.1)
URINORM ※ Uricosuric agent [Renal disease and hemodialysis]	752	513	(238)	(31.7)
Others	2,627	2,253	(374)	(14.3)

※ In-house products

### (References) Sales and ratio of in-house products

<i>(Millions of Yen)</i>	FY2017	FY2018	Change B-A	Change (%) (B-A)/A
	First nine months A	First nine months B		
Sales of in-house products	11,659	11,176	(482)	(4.1)
Ratio of in-house product sales (%)	26.0	24.9	(1.1)	-

### ③ Balance Sheet

<i>(Millions of Yen)</i>	December 31, 2017	September 30, 2018	Change	Change (%)	Component ratio (%)
	A	B	B-A	(B-A)/A	(September 30, 2018)
Current assets	83,980	80,773	(3,206)	(3.8)	77.1
Cash and deposits	6,458	3,720	(2,737)		
Deposits in the cash management system	9,836	6,951	(2,885)		
Notes and accounts receivable-trade	29,123	25,344	(3,779)		
Short-term investment securities	24,957	32,345	7,387		
Inventories	10,126	9,895	(231)		
Others	3,478	2,517	(961)		
Noncurrent assets	20,761	23,980	3,219	15.5	22.9
Property, plant and equipment	5,540	5,333	(206)		
Intangible assets	817	738	(78)		
Investments and other assets	14,403	17,908	3,505		
Investment securities	7,478	11,790	4,311		
Long-term prepaid expenses	5,748	4,994	(753)		
Others	1,176	1,123	(53)		
<b>Total assets</b>	<b>104,741</b>	<b>104,754</b>	<b>12</b>	<b>0.0</b>	<b>100.0</b>
Current liabilities	15,868	14,712	(1,156)	(7.3)	14.0
Accounts payable-trade	8,242	7,644	(598)		
Income taxes payable	1,396	333	(1,062)		
Accrued employees' bonuses	684	1,368	683		
Others	5,544	5,365	(178)		
Long-term liabilities	1,753	1,857	103	5.9	1.8
<b>Total liabilities</b>	<b>17,622</b>	<b>16,570</b>	<b>(1,052)</b>	<b>(6.0)</b>	<b>15.8</b>
Shareholders' equity	86,364	87,301	937	1.1	83.4
Unrealized gain on available-for-sale securities	745	871	126	17.0	0.8
Subscription rights to shares	9	11	1	14.3	0.0
<b>Total equity</b>	<b>87,119</b>	<b>88,184</b>	<b>1,065</b>	<b>1.2</b>	<b>84.2</b>
<b>Total liabilities and equity</b>	<b>104,741</b>	<b>104,754</b>	<b>12</b>	<b>0.0</b>	<b>100.0</b>

#### Major factors in increase/decrease

(Current assets)

Short-term investment securities : Increase with acquisition of debt securities and trust beneficiary rights

(Noncurrent assets)

Investment securities : Increase with acquisition of debt securities

#### ④ Capital Expenditures

(Millions of Yen)	FY2017	FY2018	Change	Change (%)
	First nine months	First nine months		
	A	B	B-A	(B-A)/A
Capital expenditures	650	485	(165)	(25.4)
PP&E	506	353	(152)	(30.2)
Intangible assets	144	132	(12)	(8.5)

#### Descriptions of capital expenditures

PP&E : Investment mainly in manufacturing facilities aiming to maintain and improve productivity  
 Intangible assets : Investment in software aiming to streamline operations

#### ⑤ Depreciation/Amortization

(Millions of Yen)	FY2017	FY2018	Change	Change (%)
	First nine months	First nine months		
	A	B	B-A	(B-A)/A
Depreciation and amortization of intangible assets	889	769	(120)	(13.6)
Amortization of long-term prepaid expenses	793	761	(32)	(4.1)

#### ⑥ Research and Development

Development code 「Product Name」	Indication	Formulation/ Route of administration	Development stage (domestic)					Remarks
			Phase I	Phase II	Phase III	Application	Approval	
<b>Renal disease and hemodialysis</b>								
JTT-751 「Riona® Tablets」	Iron-deficiency anemia	Oral			Phase III			<ul style="list-style-type: none"> <li>·Licensing agreement signed with Keryx for development and commercialization of hyperphosphatemia drug in Japan</li> <li>·Co-development with JT(Additional indication)</li> <li>·Riona filed by JT has been approved as a treatment of hyperphosphatemia in January 2014, and is being promoted and distributed by Torii.</li> </ul>
JTZ-951	Anemia associated with chronic kidney disease	Oral			Phase III			<ul style="list-style-type: none"> <li>·JT's original compound</li> <li>·Licensing agreement signed with JT for development and commercialization</li> </ul>
<b>Skin disease</b>								
JTE-052	Atopic dermatitis	Topical			Phase III			<ul style="list-style-type: none"> <li>·JT's original compound</li> <li>·Licensing agreement signed with JT for development and commercialization</li> </ul>
	Atopic dermatitis in children	Topical			Phase III			<ul style="list-style-type: none"> <li>·JT's original compound</li> <li>·Licensing agreement signed with JT for development and commercialization</li> </ul>
<b>Allergens</b>								
TO-203 「MITICURE® House Dust Mite Sublingual Tablets」	House dust mite induced allergic asthma (Allergen Immunotherapy)	Sublingual tablet			Phase II / III (Study completed※)			<ul style="list-style-type: none"> <li>·Licensing agreement signed with ALK for providing exclusive development and sales rights in Japan</li> <li>·In-house</li> <li>※Examining the future development policy</li> </ul>

Updates since the previous announcement on July 30, 2018

·JTE-052 for the indication of atopic dermatitis in children has entered into the clinical stage(Phase III) in Japan.

(Reference)

In October 2017, JT announced that the company signed an exclusive license agreement with EirGen Pharma Limited for the development and commercialization in Japan of calcifediol extended-release capsules (marketed by OPKO Health, Inc. in the U.S. under the brand name "RAYALDEE®") for the treatment of secondary hyperparathyroidism (SHPT) in chronic kidney disease, and Torii is expected to commercialize the product once it is approved.

### III Financial Forecasts for the FY2018

The forecasts for the FY2018 have been changed from the previous forecasts announced at the first six months of FY2018 financial results announcement on July 30, 2018.

#### ① Statement of Income

(Millions of Yen)	FY2018	FY2018	Change	FY2017	Change	Change
	previous forecast	revised forecast				
	A	B	B-A	C	B-C	(B-C)/C
Net sales	61,500	62,000	500	64,135	(2,135)	(3.3)
Sales of products	60,810	61,280	470	62,935	(1,655)	(2.6)
Renal disease and hemodialysis	21,390	21,700	310	25,276	(3,576)	(14.1)
Skin disease	9,190	9,190	-	9,905	(715)	(7.2)
Allergens	3,210	3,370	160	2,099	1,270	60.5
HIV infection	21,510	21,520	10	19,777	1,742	8.8
Other	5,510	5,500	(10)	5,877	(377)	(6.4)
Other sales	690	720	30	1,199	(479)	(40.0)
Cost of sales	31,600	31,700	100	31,293	406	1.3
Gross profit	29,900	30,300	400	32,841	(2,541)	(7.7)
SG&A	26,400	26,200	(200)	26,559	(359)	(1.4)
R&D expenses	4,700	4,400	(300)	4,608	(208)	(4.5)
Others	21,700	21,800	100	21,950	(150)	(0.7)
Operating income	3,500	4,100	600	6,281	(2,181)	(34.7)
Ordinary income	3,600	4,200	600	6,403	(2,203)	(34.4)
Net income	2,600	3,000	400	4,718	(1,718)	(36.4)

#### (Reference) Ratio to net sales

(%)	FY2018	FY2018	Change	FY2017	Change
	previous forecast	revised forecast			
	A	B	B-A	C	B-C
Cost of sales	51.4	51.1	(0.3)	48.8	2.3
SG&A	42.9	42.3	(0.6)	41.4	0.9
R&D expenses	7.6	7.1	(0.5)	7.2	(0.1)
Operating income	5.7	6.6	0.9	9.8	(3.2)
Ordinary income	5.9	6.8	0.9	10.0	(3.2)
Net income	4.2	4.8	0.6	7.4	(2.6)

#### (Cautionary Note Regarding FY2018 Forecasts)

In August 2018, JT signed a non-binding LOI for initiating a discussion with Gilead to terminate the license agreements for six anti-HIV drugs ("Viread Tablets" "Emtriva Capsules" "Truvada Combination Tablets" "Stribild Combination Tablets" "Genvoya Combination Tablets" and "Descovy Combination Tablets"). The anti-HIV drugs were developed by Gilead, and have been exclusively licensed to JT to develop and commercialize in Japan.

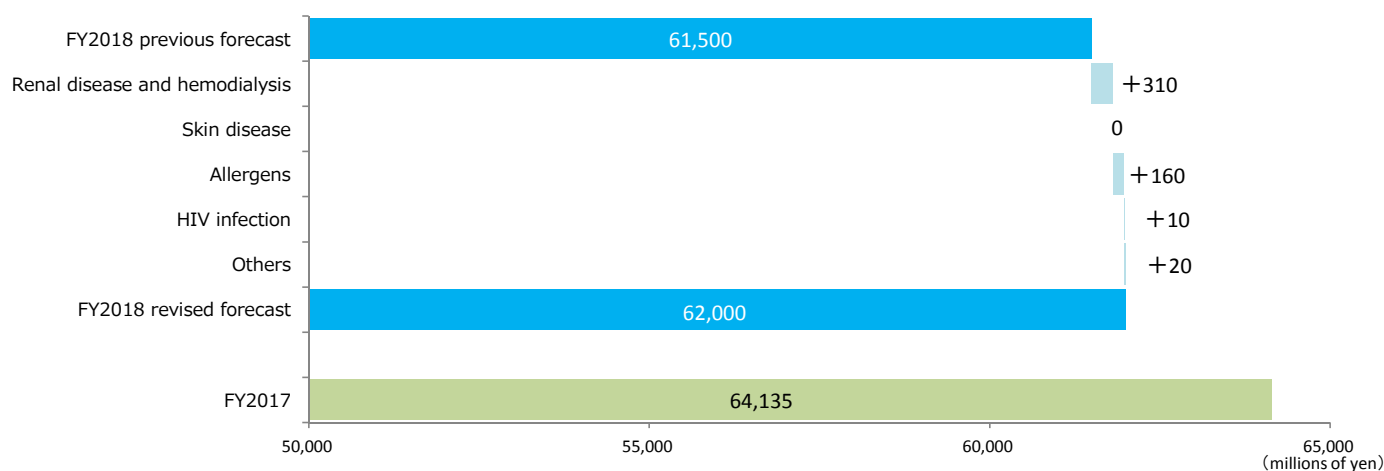
Torii and JT signed a non-binding LOI for initiating a discussion to terminate the license agreements by which JT grants Torii the exclusive rights to market the anti-HIV drugs in Japan.

The effect of the LOI on the business performance of Torii has not been incorporated in the forecasts for the FY2018. Torii will make a further announcement regarding this subject when appropriate.



**【Factors in increase/decrease compared with the previous forecast for the FY2018】**

**Net sales ( ¥ 62,000 million : Increase ¥ 500 million)**



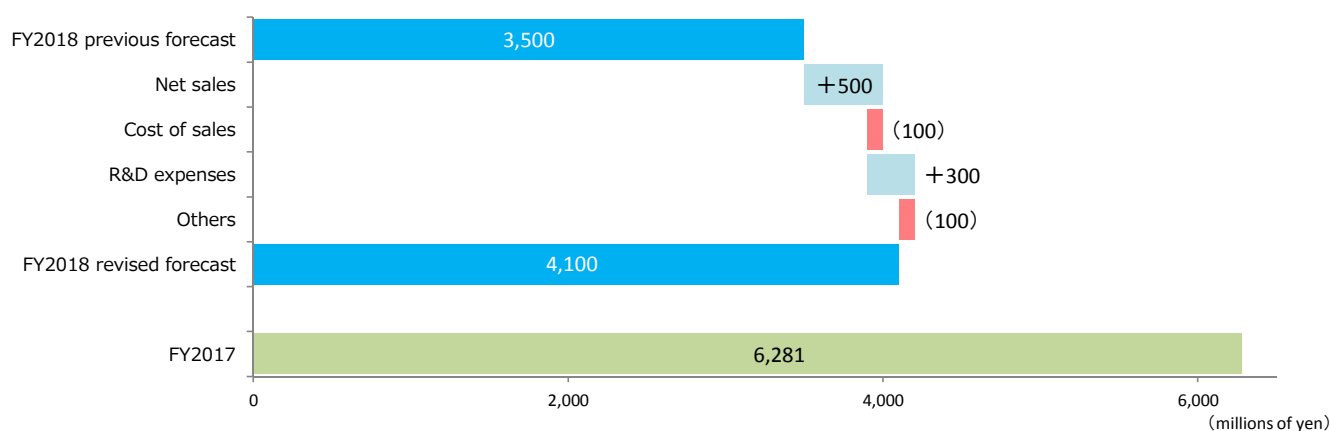
**Major factors in increase/decrease**

Renal disease : REMITCH Increase ¥ 340 million  
and hemodialysis

Allergens : MITICURE Increase ¥ 190 million

※ For details, please refer to "② Sales of Products" on page 9.

**Operating income ( ¥ 4,100 million : Increase ¥ 600 million)**



**Major factors in increase/decrease**

R&D expenses : Decrease in co-development expenses (JTS-661, JTT-751) and clinical study expenses (TO-206)

**Ordinary income ( ¥ 4,200 million : Increase ¥ 600 million)**

Special remarks: None

**Net income ( ¥ 3,000 million : Increase ¥ 400 million)**

Special remarks: None

## ② Sales of Products

(Millions of Yen)	FY2018	FY2018	Change	FY2017	Change	Change
	previous forecast	revised forecast				
	A	B	B-A	C	B-C	(B-C)/C
Sales of Products	60,810	61,280	470	62,935	(1,655)	(2.6)
Descovy Antiviral agent for HIV [HIV infection]	12,600	12,560	(40)	9,218	3,341	36.3
REMITCH Oral anti-pruritus agent [Renal disease and hemodialysis]	10,780	11,120	340	13,838	(2,718)	(19.6)
Genvoya Antiviral agent for HIV [HIV infection]	7,330	7,370	40	6,325	1,044	16.5
Riona Agent for hyperphosphatemia [Renal disease and hemodialysis]	6,860	6,760	(100)	6,245	514	8.2
ANTEBATE ※ Topical corticosteroid [Skin disease]	5,620	5,600	(20)	6,282	(682)	(10.9)
BIO-THREE Viable bacterial preparations [Other]	2,690	2,690	–	2,545	144	5.7
KAYEXALATE ※ Agent for hyperkalemia [Renal disease and hemodialysis]	1,960	1,980	20	2,123	(143)	(6.8)
CEDARTOLEN ※ Japanese cedar pollinosis (Allergen Immunotherapy) [Allergens]	1,730	1,550	(180)	1,295	254	19.6
LOCOID ※ Topical corticosteroid [Skin disease]	1,500	1,530	30	1,411	118	8.4
ZEFNART Topical antifungal agent [Skin disease]	1,480	1,470	(10)	1,483	(13)	(0.9)
Truvada Antiviral agent for HIV [HIV infection]	1,400	1,420	20	3,941	(2,521)	(64.0)
FUTHAN ※ Protease inhibitor [Renal disease and hemodialysis]	1,100	1,150	50	2,047	(897)	(43.8)
MITICURE ※ House dust mite allergy (Allergen Immunotherapy) [Allergens]	860	1,050	190	461	588	127.6
Magsent Tocolysis in threatened premature labor Eclampsia-suppressing and treatment [Other]	1,010	990	(20)	1,115	(125)	(11.2)
URINORM ※ Uricosuric agent [Renal disease and hemodialysis]	690	690	–	1,020	(330)	(32.4)
Others	3,200	3,350	150	3,579	(229)	(6.4)

※ In-house products

### (References) Sales and ratio of in-house products

(Millions of Yen)	FY2018	FY2018	Change	FY2017	Change	Change
	previous forecast	revised forecast				
	A	B	B-A	C	B-C	(B-C)/C
Sales of in-house products	15,310	15,510	200	16,323	(813)	(5.0)
Ratio of in-house product sales (%)	25.2	25.3	0.1	25.9	(0.6)	–

### ③ Capital Expenditures

<i>(Millions of Yen)</i>	FY2018 previous forecast <i>A</i>	FY2018 revised forecast <i>B</i>	Change <i>B-A</i>	FY2017 <i>C</i>	Change <i>B-C</i>	Change (%) <i>(B-C)/C</i>
Capital expenditures	1,038	958	(80)	931	26	2.8
PP&E	813	749	(64)	714	34	4.9
Intangible assets	225	209	(16)	217	(8)	(4.0)

#### Descriptions of capital expenditures

PP&E : Investment mainly in manufacturing facilities aiming to maintain and improve productivity  
 Intangible assets : Investment in software aiming to streamline operations

### ④ Depreciation/Amortization

<i>(Millions of Yen)</i>	FY2018 previous forecast <i>A</i>	FY2018 revised forecast <i>B</i>	Change <i>B-A</i>	FY2017 <i>C</i>	Change <i>B-C</i>	Change (%) <i>(B-C)/C</i>
Depreciation and amortization of intangible assets	1,058	1,050	(8)	1,174	(124)	(10.6)
Amortization of long-term prepaid expenses	964	964	–	1,061	(97)	(9.2)

### ⑤ Dividends

	FY2018 previous forecast <i>A</i>	FY2018 revised forecast <i>B</i>	Change <i>B-A</i>	FY2017 <i>C</i>	Change <i>B-C</i>	Change (%) <i>(B-C)/C</i>
Dividends per share ( ¥ )	48	48	0	48	0	0.0
Dividends payout ratio (%)	51.8	44.9	(6.9)	28.5	16.4	–

#### 【Important notes on forward-looking statements】

The forecasts presented in this material are forward-looking statements. Reflecting assumptions based on information available on the date of publication, these statements are subject to inherent risks and uncertainties. Accordingly, unforeseen factors may cause actual results to differ materially from the projections contained herein.

Torii will not necessarily revise this material regardless of any new information, future events or other results.